



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,738	11/04/2003	Brian Pope	MDX / 297	4966

26875 7590 02/12/2007
WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
----------	--------------

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/700,738

Applicant(s)

POPE ET AL.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendments submitted 29 December 2006.

Claims 1-81 are currently pending. In the Interview Summary mailed 8 December 2006, the Examiner indicated that pending further review of the applied references, the amendments proposed by the applicant would overcome the prior art of record (see Continuation Sheet). However, upon further review, the Examiner believes these amendments do not overcome the prior art of record as discussed below.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-31, 46-67, 72-74, 78, and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by JHUBOO (US 5,501,665).

Regarding claims 1, 13, 46, 55, 74, 78, 81 Jhuboo teaches a device and a method of automatically detecting an occlusion in a fluid line of a syringe pump, the syringe pump (8) including a housing (10) adapted to support a syringe (12) containing a plunger (18) moveable inside the syringe by pushing an end of a plunger with a pusher (14) to expel

Art Unit: 3767

fluid from an outlet of the syringe into a fluid line (tube shown in Figure 2) connected to the outlet and configured to carry the fluid under pressure to a patient, the method comprising: mounting the syringe onto the housing with the plunger end extended; coupling the pusher to the end of the plunger; initiating a pumping sequence to cause the fluid to flow into the fluid line; during the pumping sequence, using a sensor (36) to determine a first force value indicative of force in the fluid line at time T1; during the pumping sequence, determining a second force value indicative of force in the fluid line at time T2; and providing an indication of the occlusion if a relationship between the first and second force values departs from an expected relationship. Such a method is disclosed in Col 1 line 55- Col 2 line 43; the device is described in Col 2 line 67- Col 3 line 10.

Regarding claims 2,14,24 an alarm is triggered when an occlusion is detected; therefore a no-alarm condition indicates there is no occlusion

Regarding claims 3,15,57 a steady-state condition is determined (gradient constant)

Regarding claims 16-18, the gradient constant is determined from the startup time period and startup fluid volume, since the gradient constant is a function of the flow rate, or a function of volume and time.

Regarding claims 4,19,20,22,59 a sensor (force transducer 36) is used to determine the first and second force values.

Regarding claims 5,23,48,60 a window (time interval) is determined for T1 and T2

Regarding claims 6,25,56,58,61 an expected relationship (gradient constant) is compared to the first and second force values

Art Unit: 3767

Regarding claims 7,8,10,26,27,29,50,52,62,63,65 a trial slope (and occlusion slope, or gradient constant) (flow rate) is determined using the first and second force values and compared to an occlusion slope

Regarding claims 9,28,47,49,51,64 the expected relationship is compared to the relationship between the first and second force values to determine if an occlusion exists.

Regarding claims 11,21,30,66 a time window is shifted to obtain an additional force value

Regarding claims 12,31,67 the indication of occlusion is cancelled when the comparison between the trial slope and the occlusion slope (or gradient constant) are compared

Regarding claims 53,54,72, and 73, a third pressure measurement after time T3 is taken to be compared to the first two measurements.

3. Claims 37-44 are rejected under 35 U.S.C. 102(e) as being anticipated by TRIBE (US 2003/0205587).

Regarding claims 37 and 40 Tribe teaches a device and a method of automatically detecting an occlusion in a fluid line of a syringe pump, the syringe pump (7) including a housing (2) adapted to support a syringe (3) containing a plunger (35) moveable inside the syringe by pushing an end of a plunger with a pusher (10) to expel fluid from an outlet of the syringe into a fluid line (5) connected to the outlet and configured to carry the fluid under pressure to a patient, the method comprising: mounting the syringe onto the housing with the plunger end extended; coupling the pusher to the end of the plunger; initiating a pumping sequence to cause the fluid to flow into the fluid line;

during the pumping sequence, using a sensor (20) to determine a first force value indicative of force in the fluid line at time T1; and altering the flow rate in response to an occlusion. Such a method is disclosed in paragraphs 0005-0009.

Regarding claims 38,39,41-44, following indication of an occlusion, the fluid flow is reversed (reduced) for a time period until a predetermined level is reduced, then the user may manually restart the pump after the delay period.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 32,34,36,68,70,76,77 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13,55,74 and 78 above, and further in view of Tribe.

As disclosed above, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an occlusion exists. Jhuboo does not discuss altering the fluid flow rate beyond the indication to the user that an occlusion exists via an alarm.

Tribe teaches that an automatic syringe pump can be controlled by an occlusion detector to reverse the flow rate and require manual restart of the pump after an occlusion has occurred (P0005-0009).

Art Unit: 3767

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the automatic fluid delivery rate controls of Tribe in order to make the pump easy to use and to prevent the user from either ignoring or failing to response to the alarm signals.

6. Claims 33,35,45,69,71,75, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jhuboo as applied to claims 13,40,55,74 and 78 above, and further in view of MOBERG (US 6,485,465).

Regarding claims 33,35,45,69,71,75, and 79, Jhuboo teaches an occlusion detector where the slope of two forces over a time interval is compared to a gradient constant to determine if an occlusion exists. Jhuboo does not discuss the delivery of a bolus from the infusion pump, however any syringe pump is capable of bolus delivery.

Moberg teaches an infusion pump (101) and force occlusion detector (134). Moberg teaches that the occlusion detector automatically responds to force greater than the maximum allowable bolus delivery (Col 6 3rd paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the occlusion detector of Jhuboo with the bolus occlusion detection of Moberg in order to prevent a false occlusion alarm resulting in the delivery of a prescribed bolus dose.

7. Claims 1-31, 46-67,72-74,78, and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by JHUBOO (US 5,501,665).

Jhuboo teaches the limitations of the claims as described above, but uses an average pressure, determined from instantaneous pressure values. It would have been obvious

to one of ordinary skill in the art at the time the invention was made to use instantaneous pressure values since the general progression in the art of pressure detection systems has been to move from instantaneous pressure values to average pressure values. See Jhuboo Col 1 lines 15-32. The present invention seems to be the precursor to the invention of Jhuboo.

Allowable Subject Matter

7. The following claims drafted by the examiner and considered to distinguish patentably over the art of record in this application, are presented to applicant for consideration:

As an example, in claim 1: following the step of "initiating a pumping sequence to cause the fluid to flow into the fluid line;"

During the pumping sequence, using a sensor to measure instantaneous force value F_1 indicative of force in the fluid line at instantaneous time T_1 ; during the pumping sequence, using the sensor to measure instantaneous force value F_2 indicative of force in the fluid line at instantaneous time T_2 ; and providing an indication of occlusion if a gradient calculated by dividing only the difference between instantaneous force F_2 from instantaneous force F_1 by the difference in time between instantaneous time T_2 from instantaneous time T_1 exceeds a predetermined threshold gradient.

Response to Arguments

8. Applicant's arguments filed 29 December 2006 have been fully considered but they are not persuasive. The amendments require that a sensor determines

instantaneous first and second force values, and uses "a relationship" between the values to signal an occlusion. The method of Jhuboo uses the relationship of an average between the first and second force values to determine if an occlusion exists and therefore meets the claim language.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

Art Unit: 3767

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elizabeth MacNeil
1129107

Alvin
KIMBERLY D. LUGGINS
SUPERVISOR, EXAMINER
TECHNICAL STAFF